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Gap Analysis for IMBA and DOE Safety Software Central Registry Recommendation

Final

U.S. Department of Energy
Office of Environment, Safety and Health
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FOREWORD

This report documents the outcome of an evaluation of the safety software quality assurance attributes of the Integrated Modules for Bioassay Analysis (IMBA) Expert ™ USDOE-Edition and Professional Plus computer products relative to the safety software requirements identified in DOE O 414.1C, *Quality Assurance*. This evaluation, a gap analysis, is performed according to DOE G 414.1-4 and is a requisite for deciding whether IMBA should be designated as a toolbox code for the Safety Software Central Registry of the U.S. Department of Energy. Comments regarding this document should be addressed to:

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EXECUTIVE SUMMARY

The development and maintenance of a collection, or toolbox, of high-use, U.S. Department of Energy (DOE) safety software quality assurance (SSQA)-compliant codes is one of the major improvement actions supported under DOE O 414.1C, *Quality Assurance*, and DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C Quality Assurance*. Integrated Modules for Bioassay Analysis (IMBA) Expert™ USDOE-Edition (IX) version 4.0.28, IMBA Professional Plus (IPP) version 4.0.28, and all future IPP version 4.0.x minor releases are being considered for the DOE Safety Software Central Registry.

To evaluate IMBA Expert™ USDOE-Edition version 4.0.28 and IPP version 4.0.28 compliance with SSQA requirements, a software-specific gap analysis is necessary. SSQA requirements are those documented in DOE O 414.1C. The gap analysis evaluates the SSQA attributes against the identified work activities specified in DOE O 414.1C and DOE G 414.1-4. The evaluation documented herein provides the results of the gap analysis for the IMBA products and versions specified above and recommends whether these products and versions should be added to the DOE Safety Software Central Registry.

Based on the outcome of the gap analysis, IMBA Expert™ USDOE-Edition version 4.0.28, IPP version 4.0.28, and all future minor releases of IPP 4.0.x are recommended for inclusion in the DOE Safety Software Central Registry contingent upon the five critical recommendations being implemented by the United Kingdom's Health Protection Agency (HPA) and the DOE Office of Environment, Safety and Health (EH) and reviewed by the Central Registry program lead. Of the eleven work activities evaluated, three work activities were fully met, two were partially met, and six were not met. Two work activities (problem reporting and corrective actions and software configuration management) include critical recommendations that, if implemented properly, will increase the level of compliance for the work activities to full and partial, respectively.

The evaluation determined that IMBA fully met the criterion of model validation/performance. This criterion is one of the most important and is specific for software being considered as a toolbox code in the DOE Safety Software Central Registry. The evaluation determined through this criterion that IMBA products implement industry accepted scientific methods for solving internal dosimetry scenarios correctly. Although the verification and validation work activity was determined to be partially met, the key testing sub-activities were identified as being robust, repeatable, and consistently implemented. Results from validation activities indicate that a high-quality product is delivered to DOE users. Currently, IMBA products are in the software maintenance phase that may include significant future enhancements. The IMBA project staff is a small group of highly skilled internal dosimetrists who implement the work activities consistently. Although several of the work activities were only partially met or not met, this has not resulted in any significant defects being released to the users.

There are five critical recommendations that directly affect the DOE user. Prior to DOE including the IMBA products in the DOE Safety Software Central Registry, it is recommended that HPA develop work practices to implement these recommendations. Three of the recommendations are related to software configuration management (work activity 3) and two are related to problem reporting and corrective actions. Two of the recommendations are associated with IMBA Expert™ USDOE-Edition and the other three recommendations with IPP. Recommendation R9-1 requires implementation by EH. These critical recommendations are listed below.

CritRec 1. R3-1: Provide IMBA Expert™ USDOE-Edition V 4.0.28 directly to each licensed DOE user. The recommended distribution method is a CD. This type of distribution will assure that all authorized DOE users have the correct software components, since the automatic or

manual updates for IMBA Expert™ USDOE-Edition have not functioned properly for all DOE users.

CritRec 2. R3-2: Create a unique identifier associated with the IPP sub-modules and implement the use of this identifier throughout development and distribution.

CritRec 3. R3-3: Provide a more obvious and consistent method to confirm that the most recent versions of all sub-modules are being used or downloaded.

CritRec 4. R9-1: Establish and implement an EH problem reporting and notification procedure for IMBA Expert™ USDOE-Edition. (Note: This is a recommendation for EH).

CritRec 5. R9-2: Implement a formal program with explicit procedures and more accessible records of corrective action activities.

The evaluation team has additional recommendations that should be considered as future improvements for IMBA products and processes. The recommendations are included in each work activity section in this document.

1. Introduction

The development and maintenance of a collection, or toolbox, of high-use, U.S. Department of Energy (DOE) safety software quality assurance (SSQA)-compliant codes is one of the major improvement actions supported under DOE O 414.1C, *Quality Assurance*. This collection of toolbox codes is referred to as the DOE Safety Software Central Registry. The DOE Office of Environment, Safety and Health's (EH) *Management System for Quality and Safety Management* establishes DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, as the implementation strategy for the Central Registry. Integrated Modules for Bioassay Analysis (IMBA)[1] Expert™ USDOE-Edition version 4.0.28 and IMBA Professional Plus (IPP) version 4.0.28 are being considered for the Central Registry.

To evaluate IMBA Expert™ USDOE-Edition version 4.0.28 and IPP version 4.0.28 compliance with SSQA requirements, a software-specific gap analysis is performed according to the process described in DOE G 414.1-4. SSQA requirements are those documented in DOE O 414.1C. The gap analysis evaluates the SSQA attributes against the identified work activities specified in DOE O 414.1C and DOE G 414.1-4.

In the sections that follow, IMBA Expert™ USDOE-Edition and IPP are defined as IMBA *products*. Each of these products can include multiple versions.

1.1 Objectives

The intent of the gap analysis is to evaluate the IMBA products and versions specified above and recommend to EH whether these products and versions should be added to the DOE Safety Software Central Registry.

1.2 Description of IMBA

Starting in the mid 1980's, a number of computer codes for the evaluation of bioassay data and calculation of internal dose became commercially available. These codes, including but not limited to GENMOD, INDOS, REMEDY, and CINDY, were based on the models and methodology of the International Commission on Radiological Protection (ICRP) Publication 26 and the 30 series of reports. The ICRP published new, more complex, and comprehensive internal dosimetry models and methods starting in 1994 with the issuance of ICRP Publication 66, *Human Respiratory Tract Model* (HRTM). A series of new systemic models were published shortly thereafter in ICRP publications 67, 68, 69, and 71. As of the mid 1990's, the existing computer codes were unable to use the new HRTM and systemic models, and the codes were never upgraded to incorporate these models. To fill this gap, in 1997 British Nuclear Fuels, Westlakes Research Institute, and the United Kingdom (U.K.) National Radiological Protection Board (NRPB) started development of a computer code[2] that would incorporate the new models. This code actually comprised a series of independent modules that performed specific tasks and communicated with each other though input/output files. For this reason, the code was called Integrated Modules for Bioassay Analysis, or IMBA.

In 2001, the NRPB, whose functions were absorbed later into the U.K. Health Protection Agency (HPA), and ACJ & Associates started development of a user-friendly interface for the IMBA modules. This effort was funded in part by the U.S. DOE, and in 2003 the first version of IMBA Expert™ USDOE-Edition was distributed to the following participating sites:

1. Office of Worker Protection Programs (EH-52) [now the Office of Quality Assurance Programs (EH-31)], DOE, Washington, D.C.

[1] Other IMBA products such as IMBA Expert™ ORAU-Edition are not addressed in this gap analysis.

[2] A. Birchall, N.S. Jarvis, M.S. Peace, A.E. Riddell, W.P. Battersby, *The IMBA Suite: Integrated Modules for Bioassay Analysis* Radiation Protection Dosimetry (79) 1-4: 107-110, 1998.

2. Pacific Northwest National Laboratory, Richland, WA
3. Savannah River Site, Aiken, SC
4. Los Alamos National Laboratory, Los Alamos, NM
5. Lawrence Livermore National Laboratory, Livermore, CA
6. BWXT Y-12 Plant, Oak Ridge, TN
7. Sandia National Laboratories, Albuquerque, NM

The final version of IMBA Expert™ USDOE-Edition was delivered in 2004. Other, customized versions of IMBA were developed for specific users, including the Canadian power reactor industry and for the U.S. National Institute for Occupational Safety and Health. In 2005, IPP was introduced. This version of IMBA incorporated most of the functionality offered in previous versions of IMBA and was designated as the IMBA version to be supported and enhanced in the future. At the issuance of this report, IPP remains the only commercially available software to evaluate bioassay data and calculate internal dose with the newer ICRP models. Formal support for IMBA Expert™ USDOE-Edition will end in December 2006[3].

To be considered for inclusion in the DOE Safety Software Central Registry as a toolbox code, software must meet basic criteria. Table 1-1 provides a summary of the justification for IMBA products toward meeting these basic criteria.

Table 1-1. Justification for Considering IMBA as Safety Software Toolbox Code

Criterion	Justification
• Widespread use of the software across the DOE complex for safety-related applications.	Based on a survey of DOE contractors (*Survey Summary on Use of IMBA in DOE Complex*, February 2006), approximately 14 DOE health protection organizations use the IMBA Expert™ USDOE-Edition. There is no other commercial application that serves this function on as widespread a basis.
• Meets definition of *safety software*. Safety Software (from DOE O 414.1C). Includes the following: (1) Safety System Software. Software for a nuclear facility2 that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, *Safety Management System Policy,* dated 10-15-96, and the DEAR clause. (2) Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.	IMBA Expert™ USDOE-Edition and IPP software are used to evaluate doses to DOE workers resulting from intakes of radioactive materials in the workplace. The doses are used to demonstrate compliance with the requirements of 10 CFR 835.402. It therefore meets definition (3), i.e., *Software that performs a hazard control function in support of a radiological safety management program.*

[3] A. Birchall, HPA, Correspondence to R. Loesch, (April 19, 2006)

Criterion	Justification
(3) Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirement or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause.	
• Demonstrated and quantifiable benefit for designating the software to the DOE Safety Software Central Registry.	IMBA has been, and appears to be for the foreseeable future, the likely standard for bioassay analysis among the DOE radiological protection organizations. Thus, by designating this software for the DOE Safety Software Central Registry, consistency in the area of bioassay analyses will be promoted among DOE sites and laboratories. Furthermore, the guidance document reduces the likelihood of inappropriate use of the software.

1.3 Software Type and Grade Level Designation

As the supporting discussion details in the balance of this report, IMBA Expert™ USDOE-Edition meets the characteristics of custom developed safety software as described in DOE G 414.1-4. While IPP can be considered commercial software, it was derived from IMBA Expert™ USDOE-Edition, and for purposes of this gap evaluation it will be treated as custom-developed software. In summary, both IMBA products are evaluated as custom-developed software.

On the basis of DOE G 414.1-4 and information received in the DOE survey[4] on IMBA use and applications, an IMBA software failure could result in incorrect recording of hazardous (radiological) exposures to workers. The software thus meets B grading level criteria as defined in DOE G 414.1-4. Therefore, for the IMBA products used for DOE applications, the Level B software grade level is justified (Table 1-2).

Table 1-2. Software Grade Level Confirmation

Software Level	Check all that apply	Criteria for Grading Level
A. This grading level includes safety software		• Software failure that could compromise a limiting condition for operation.

[4] *Survey Summary on Use of IMBA in DOE Complex*, February 2006

applications that meet one or more of the following criteria.		• Software failure that could cause a reduction in the safety margin for an SSC that is cited in DOE approved documented safety analysis.
		• Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either (a) a DOE approved documented safety analysis or, (b) an approved hazard analysis per DOE P 450.1, *Safety Management System Policy* and the DEAR ISMS clause.
		• Software failure that could result in non-conservative safety analysis, design or misclassification of facilities or SSCs
B. This grading level includes safety software applications that do not meet Level A criteria but meet one or more of the following criteria.		• Safety management databases used to aid in decision making whose failure could impact safety SSC operation.
	√	• Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or the public.
		• Software failure that could compromise the defense in-depth capability for the nuclear facility.
C. This grading level includes software applications that do not meet Level B criteria but meet one or more of the following criteria.	N/A	• Software failure that could cause a potential violation of regulatory permitting requirements.
		• Software failure that could affect environment, safety, health monitoring or alarming systems.
		• Software failure that could affect the safe operation of an SSC

The ten work activities, as defined in DOE G 414.1-4, are evaluated in this report. The evaluation process for inclusion into the DOE Safety Software Central Registry adds an eleventh work activity to address model validation/performance work activities carried out in the development of the IMBA products. The graded approach, as specified in DOE G 414.1-4, is applied to the eleven work activities (Table 1-3). The term *Full* implies that all elements of the work activity must be addressed. The term *Grade* allows some elements of the work activity to be optional or implemented with less rigor.

Table 1-3. Work Activities and Applicability of DOE G 414.1-4 Criteria for IMBA Products

Work Activity	Applicability
1. Software project management and quality planning	Full
2. Software risk management	Grade
3. Software configuration management	Full
4. Procurement and supplier management	Full
5. Software requirements identification and management	Full
6. Software design and implementation	Full
7. Software safety	Grade
8. Verification and validation (V&V)	Grade
9. Problem reporting and corrective action	Full

10. Training personnel in the design, development, use, and evaluation of safety software	Grade
11. Model validation/performance	Full

2. IMBA Summary

The gap analysis of the IMBA products considered a body of information that describes the code and its development, characteristics, strengths, operating parameters, and other pertinent information. Detailed below are a general overview of IMBA (Table 2-1), contact information for the IMBA sponsor and evaluator (Table 2-2), and the documentation reviewed (Table 2-3).

Table 2-1. Overview of IMBA Software Application

Type	Specific Information
Version(s) of IMBA	• IMBA Expert™ USDOE Version 4.0.28 • IMBA Professional Plus Version 4.0.28
Developing Organizations and Sponsor Information	ACJ & Associates and the HPA worked together on the development of IMBA Expert™ USDOE-Edition. HPA has recently taken over complete responsibility for IPP.
Auxiliary Software Products	IMBA Expert™ USDOE-Edition contains eight sub-modules. The auxiliary software listed here are add-ons to IPP that provide additional functionality over what exists with IMBA Expert™ USDOE-Edition. • Statistical add-on • Compensation add-on • ORTEC® add-on
Software Platform/Portability	Microsoft® Windows
Coding and Computer(s)	Visual Basic® Power Basic®
Technical Support Point of Contact	HPA – Radiation Protection Division (HPA-RPD), Chilton, Didcot, Oxfordshire, OX11 0RQ U.K.
Code Procurement Point of Contact	HPA-RPD, Chilton, Didcot, Oxfordshire, OX11 0RQ U.K.
Contributing Organization(s)	N/A – As proprietary software, IMBA has not been submitted to a software center for general use.
Recommended Documentation - Supplied with Code Transmittal upon Distribution or Otherwise Available	Each product has its own set of documentation that comprises the following: • User's Manual • Appendix A - Technical Basis • Appendix B - Bioassay Quality Assurance • Appendix C - Dose Quality Assurance • Appendix D - Example Bioassay Cases

Type	Specific Information
Input Data/Parameter Requirements	One must specify the radionuclide and the parameters of the intake and the biokinetic model. Although there can be hundreds of parameters in a model, they are easily specified through the use of defaults and standard combinations. Bioassay data must also be entered.
Summary of Output	IMBA produces output in a simple text-file format that is suitable for pasting into other applications. All input parameters and results are available in the output, if desired. On-screen output of plots is provided, but output to files requires a screen capture.
Nature of Problem Addressed by Software	IMBA includes the following capabilities: • assess an intake from bioassay measurement data • calculate bioassay quantities at different times after a specific intake • calculate equivalent organ doses and effective dose from a single intake
Significant Strengths of Software	As of the issuance of this report, IMBA remains the only commercially available software of its kind that implements the ICRP 66/67/68 biokinetic models and methods. The documentation provided with IMBA is generally regarded by users as being comprehensive and of excellent quality. IMBA has a very friendly user interface.
Known Restrictions or Limitations	IMBA does not implement independent kinetics for daughters of radionuclides like Th-232, which results in overestimates of dose (note that bioassay evaluation functions are not impacted by this limitation). Addition of new radionuclides into the IMBA library and modification of existing biokinetic models is a rather involved process that can not be performed by the typical user.[5] IMBA is also limited to 200 data points and 10 intakes.
Preprocessing (set-up) time for Typical Safety Analysis Calculation	A complex case with a lot of bioassay data may require 5-10 minutes to set up. Data can be written to and read from IMBA data files. Bioassay and related data can also be pasted into IMBA from spreadsheets.
Execution Time	Execution time for an intake evaluation not involving daughters is typically under 1 minute.
Computer Hardware Requirements	No special hardware is required.
Computer Software Requirements	Windows 98 through XP
Other Associated Software Products	• Expert™ OCAS (ORAU)-Edition • Expert™ CANDU-Edition • IMBA Expert™ UK-Edition

[5] Add-ons are being planned for Summer/Fall 2006 to include all ICRP 38 nuclides.

Table 2-2. Contact Information for IMBA Sponsor and Evaluator

Category of Information	Specific Information
Software Evaluation Sponsor:	U.S. Department of Energy Office of Quality Assurance Programs
Point of Contact: Organization: Telephone: Email:	Robert Loesch Office of Quality Assurance Programs, EH-31/270CC U.S. Department of Energy 1000 Independence Avenue, S.W. Washington, D.C. 20585-0270 (301) 903-4443 robert.loesch@eh.doe.gov
Software Evaluator Organization:	U.S. Department of Energy Office of Quality Assurance Programs
Point of Contact: Organization: Telephone: Email:	Debra R. Sparkman Office of Quality Assurance Programs, EH-31/270CC U.S. Department of Energy 1000 Independence Avenue, S.W. Washington, D.C. 20585-0270 (301) 903-6888 Debra.Sparkman@eh.doe.gov

Table 2-3. IMBA Documentation Reviewed

No.	Documents Reviewed
1.	James, A.C., Birchall, A., Marsh, J.W., Puncher, M., *User Manual for IMBA Expert™ USDOE-Edition (Phase II) Version 3.2*, April 2004.
2.	DOE Contract for the development of IMBA Expert™ USDOE-Edition, July 2005.
3.	Birchall, A., Puncher, M., James, A.C., Marsh, J.W., Jarvis, N.S., Peace, M.S., Davis, K., King D.J., *IMBA Expert™: Internal Dosimetry Made Simple* Radiation Protection Dosimetry (105), pp. 421-425, 2003
4.	Software Co-Development and Distribution Agreement dated 19 June 2000 (8 March 2001) and Technical Annex A – Proposal to Develop Internal Dosimetry Software.
5.	IMBA Professional Plus update website, http://www.hpa.org.uk/radiation/publications/software/imbapro_plus/imbaupdates.htm
6.	James, A.C., Birchall, A., Marsh, J.W., Puncher, M., *User Manual for IMBA Professional Plus, (Version 4.0),* May 2005.

No.	Documents Reviewed
7.	James, A.C., et al, *User Manual for IMBA Expert™ USDOE-Edition (Phase II) Version 3.2, Appendix A: Technical Basis*, April 2004.
8.	James, A.C., et al, *User Manual for IMBA ExpertTM USDOE-Edition (Phase II) Version 3.2, Appendix B: Bioassay Quality Assurance*, March 2004.
9.	James, A.C., et al, *User Manual for IMBA ExpertTM USDOE-Edition (Phase II) Version 3.2, Appendix C: Dose Quality Assurance*, March 2004.
10.	*User Manual for IMBA Expert™ USDOE-Edition (Phase II) Version 3.2 Appendix D: Bioassay Example Cases*, March 2004.
11.	*QA Summary*, including "cast-in-stone" QA, (pg. 23), date unknown.
12.	Birchall, A., Jarvis, N.S., Peace, M.S., Riddell, A.E., Battersby W.P., *The IMBA Suite: Integrated Modules For Bioassay Analysis* Radiation Protection Dosimetry (79), Nos. 1-4, pp. 107-110, 1998
13.	Marsh, J.W., Jarvis, N.S., Birchall, A., James, A.C., Peace, M.S., Davis, K.E., Dorrian, M.D., Phipps, A.W., Smith, A., Smith, F.M.G., *Validation of IMBA and IMBA Expert™* . Proceedings of the European IRPA Congress 2002: "Towards harmonisation of radiation protection in Europe," Florence, Italy, 8-11 October 2002.
14.	James, A.C., Birchall, A., Marsh, J.W., Puncher, M., *IMBA Professional Plus (Version 4.0) User Manual Appendix B: Bioassay Quality Assurance*, August 2005.
15.	James, A.C., et al, *IMBA Professional Plus (Version 4.0) User Manual Appendix C: Dose Quality Assurance*, August 2005.
16.	James, A.C., et al, *IMBA Professional Plus (Version 4.0) User Manual Appendix A: Technical Basis*, August 2005.
17.	James, A.C., et al, *IMBA Professional Plus (Version. 4.0) User Manual, Appendix D: Example Bioassay Cases*, August 2005.
18.	Birchall, A., Marsh, J.W., Davis, K., Bailey, M.R., Jarvis, N.S., Peach, A.D., Puncher, M., Dorrian M.D., James, A.C., *Using IMBA Professional Plus to estimate intakes and doses* SRP, 2005.
19.	IMBA Expert Bugs Report, date unknown.
20.	Resumes of Alan Birchall, Alan Phipps, Katie Davis, Marie Denise Dorrian, Naomi Jarvis, James Marsh, Mathew Puncher, and Tony Riddell, May 2006.

3. Review of IMBA Work Activities

Details on the evaluation process relative to the requirements and the criteria that are met in compliance with DOE G 414.1-4 are covered in sections 3.1 through 3.11 of this report. The review method consisted of reviewing specific work activity criteria against the information contained in documentation as identified in each of the eleven sections. The gap analysis evaluation also used personal communications that included:

- Emails
- Telephone conversations
- Discussions with one or more members of the IMBA development organizations

The work activities for IMBA are evaluated based upon the grade level of the safety software and the applicable software type. In the sections that follow, five qualitative values are used to evaluate whether a specific criterion is met:

- Yes – Evidence is available to confirm that the program, practices, and/or procedures followed in developing the software satisfy the criterion.
- No – Sufficient evidence does not exist to demonstrate the criterion is met.
- Partial – Some evidence exists that the criterion is met but has not been finalized or is incomplete.
- Uncertain – No basis is available to confirm that the criterion is met.
- N/A - The requirement is not applicable.

For the eleven work activity sections, tables are provided to individually record the evaluation of IMBA Expert™ USDOE-Edition and IPP and to document summary comments on the basis for the specific evaluation. If a distinction is drawn between the evaluations for IMBA Expert™ USDOE-Edition and IPP, the reasoning is given. Otherwise, the comments are applicable to both products. An overall determination was made whether the software meet, do not meet, or partially meet the work activity requirements as reflected in the evaluation criteria. The overall determination is recorded in the first subsection (X.1) for each of the work activities.[6] Sub-section X.2 lists the information sources that were used in the review. Sub-section X.3 provides the software quality assurance-related issues or concerns. A final sub-section X.4 identifies the major recommendations for the specific work activity from the gap evaluation team.

3.1 Software Project Management and Quality Planning

3.1.1 Work Activity Evaluation and Results

Table 3.1-1 lists the criteria reviewed for this work activity and summarizes the findings for both products. Of the six criteria evaluated for this requirement, one is not met, three are partially met, and two are uncertain. Thus, the requirement is evaluated as not met for both IMBA Expert™ USDOE-Edition and IPP.

3.1.2 Information Sources for Review

The two software development contracts for IMBA Expert™ USDOE-Edition and the two user manuals were the primary sources of information for this work practice. These are referenced in Table 2-3 (Refs. 1, 2, 3, and 4).

[6] *X* represents the index for the work activity, 1 through 11.

3.1.3 Software Quality Assurance-Related Issues or Concerns

This work activity is basic to the overall development of a software application and was partially conducted. However, software project management and quality planning work activities were not formally documented.

3.1.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R1-1: Document a comprehensive and complete software project management and quality assurance plan for IPP, following DOE G 414.1-4, or its successor, as an acceptable method for meeting this recommendation.

Table 3.1-1 Evaluation of Software Project Management and Quality Planning

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.1-1.1	Are the software specific activities and tasks described, identified and documented?	No	No	Software project management and quality assurance activities have not been documented.
3.1-1.2	Are these activities and tasks sufficient to properly manage and control the software project and produce the required level of quality?	Uncertain	Uncertain	Given that the documentation is not available, it is not possible to judge whether software project management and quality planning activities and tasks are sufficient.
3.1-1.3	Do these plans identify the organizational structure associated with the project management and quality planning?	Partial	Partial	The IPP user's manual identifies the development team and their roles.
3.1-1.4	Are these plans initiated early and maintained throughout the software development life cycle?	Uncertain	Uncertain	It is not apparent that a formal plan was developed.
3.1-1.5	Are these plans reviewed, approved and controlled?	Partial	Uncertain	Several elements of software project management planning are discussed in the contractual agreements for IMBA Expert™ USDOE-Edition.
3.1-1.6	Do these activities and tasks include the following: a. Software project schedule? b. Software project scope? c. Software engineering activities, including software requirements and design? d. Software V&V activities, including reviews and test? e. Software configuration	Partial	Uncertain	While formal documentation such as a software project management plan (SPMP) or an SQA plan (SQAP) were not developed, the contracts for DOE-Expert discuss: a. schedule b. scope c. software requirements and design d. reviews and tests e. standards, practices, conventions, and metrics

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	management (SCM) activities? f. Software risk management approach? g. Software safety analysis and planning? h. Supplier control? i. User and software staff training? j. Standards, practices, conventions, and metrics? k. Records and document collection, maintenance, and retention? l. Problem reporting and corrective action methods?			f. problem reporting and corrective action methods.

3.2 Software Risk Management

While the software development of IMBA required good clear technical planning and management of risks, there is no formal documentation that software risk was evaluated. No response has been received from inquiries on the level and depth of software risk management for the IMBA products.

3.2.1 Work Activity Evaluation and Results

Table 3.2-1 lists the criteria reviewed for this work activity and summarizes the findings for both products. Of the six criteria evaluated for this requirement, one is not met and five are uncertain. Thus, the requirement is evaluated as not met for either IMBA Expert™ USDOE-Edition or IPP.

3.2.2 Information Sources for Review

The two development contracts were the primary sources of information for this work practice. These are referenced in Table 2-3 (Refs. 2 and 4). A response to a personal communication on April 29, 2006 for elicitation of risk management work activities was not received.

3.2.3 Software Quality Assurance-Related Issues or Concerns

A formal software risk management plan, procedure, or process for the DOE Expert™ version is not a critical issue for continued use of the software, especially with respect to IPP. However, it is important to document significant software risk management work activities with sufficient rigor.

3.2.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R2-1: Document in the software project management and quality assurance plan (see R1-1) any significant software risks and how the risks will be managed.

Table 3.2-1 Evaluation of Software Risk Management

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.2-1.1	Have the risks associated with the successful completion of the software development or procurement been identified and documented?	No	No	There is no documentation available to infer that software risk management was considered with either products of IMBA.
3.2-1.2	Do these risks include risks associated with costs, resource availability, schedule, and technical aspects? Examples include: a. Incomplete or volatile software requirements; b. Specification of incorrect or overly simplified algorithms or algorithms that will be very difficult to address within safety software; c. Hardware constraints that limit the design; d. Potential performance issues with the design; e. A design that is based upon unrealistic or optimistic assumptions; f. Design changes during coding; g. Incomplete and undefined interfaces; h. Using unproven computer and software technologies such as programming languages not intended for the target application; i. Use of a programming language with only minimal experience using the language; j. New versions of the operating system; k. Unproven testing tools and test methods; l. Insufficient time for development, coding, and/or testing; m. Undefined or inadequate test acceptance criteria; n. Potential quality concerns with subcontractors or	Uncertain	Uncertain	No written documentation is available.

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	suppliers			
3.2-1.3	Have risk thresholds been identified and applied?	Uncertain	Uncertain	No written documentation or information has been made available to address this area.
3.2-1.4	Are the risks evaluated for impact and probability of occurrence initially and periodically through the software life cycle?	Uncertain	Uncertain	No written documentation or information has been made available to address this area.
3.2-1.5	Are the risks prioritized and tracked through the software life cycle?	Uncertain	Uncertain	No written documentation or information has been made available to address this area.
3.2-1.6	Are actions taken to mitigate the risks using avoidance, risk reduction, and/or transfer of risks approaches?	Uncertain	Uncertain	No written documentation or information has been made available to address this area.

3.3 Software Configuration Management

Manual undocumented processes exist to control and uniquely identify the configuration of each IMBA version. A configuration baseline is defined and is manually controlled. This baseline only includes source and compiled code.

IMBA products use both a numeric designator and a date to identify the distributed modules. For the main module, IMBA.exe, and Update.exe, a three-part numeric identifier is used. The left portion is used to indicate the major version number; and the right portion indicates the minor version. The use of the middle portion is unknown. For all versions in this evaluation, the middle portion was zero. A major version is one in which the results of the cast-in-stone automated testing has identified differences in the calculational values. A minor change is a change that is not expected to impact calculational values. A two-part numeric designator and a date format are used for the sub-modules. The two-part designator conforms to the major and minor portions described for the main and update modules.

Changes are informally evaluated by the HPA staff. Proposed changes related to defects are documented in a problem and reporting spreadsheet. Changes performed are documented in both the source code and in a text file sent from the HPA staff to the IMBA chief architect performing the official modifications. Impact and feasibility are informally discussed and reviewed by HPA staff.

Only approved changes are made. There is no formal documented change approval process. The IMBA development team is small. Verbal and email communication is used to evaluate and approve changes.

The SCM tool, Visual SourceSafe, is used to archive the configuration baseline but is not used to its full capabilities. Manual processes that provide independent review are used for both IMBA Expert™ USDOE-Edition and IPP. The source code is modified by IMBA development staff and then transferred to the IMBA chief architect for review and official modification of the master source code. The source code is compiled and then the source and compiled code is archived in Visual SourceSafe. This process creates redundant work.

3.3.1 Work Activity Evaluation and Results

Table 3.3-1 lists the criteria reviewed for this work activity and summarizes the findings for both products. Of the nine criteria evaluated for this requirement, six are met, two are not met, and one is

partially met. Thus, the requirement is evaluated as not met for either IMBA Expert™ USDOE-Edition or IPP.

3.3.2 Information Sources for Review

The primary sources of information for this work practice were personal communications. The IPP update website, http://www.hpa.org.uk/radiation/publications/software/imbapro_plus/imbaupdates.htm, was referenced for information regarding manual downloads of software. This site is referenced in Table 2-3 (Ref. 5).

3.3.3 Software Quality Assurance-Related Issues or Concerns

The SCM tool, Visual SourceSafe, is used to archive the configuration baseline but is not used to its full capabilities. The manual process creates redundant work that is not efficient.

Software testing is performed only for major changes. All non-calculational changes such as modifications to reports and displayed text are released without cast-in-stone testing. The determination of major and minor changes is based upon the expert knowledge of the software development staff. The lack of testing for minor releases increases the risks that inadvertent defects are introduced and released.

The numeric designator and date identifiers do not uniquely identify the sub-modules. A version number is used during the development phase while a date is used during the distribution phase. The date during the distribution phase can vary depending upon the method used to download and install the sub-module. As an example, Jaba_fit.exe has two different dates associated with version 2.4, 25 November 2004 and 5 May 2005.

IMBA Expert™ USDOE-Edition provides for automatic updates from a menu option. However, to use this feature, a manual download from the IMBA website of the Update.exe file is required. This file then needs to be executed to update the main program of IMBA Expert™ USDOE-Edition to display the Update menu option. Using the official IMBA web site URL as of July 2006, the evaluation team was unable to locate the website for the manual download of Update.exe. Because of the unavailability of the web site, this feature does not function properly. Thus several DOE users have been unable to download newer versions of IMBA Expert™ USDOE-Edition. Since access to Update.exe is also required for IPP, some IPP users have reported that the automatic update feature does not update the IMBA sub-modules. This feature is expected to be corrected with the publication of a new IMBA web site in Fall 2006.

Using the manual update feature, it is difficult to determine if the latest files are being currently installed on the user's computer or if a sub-module update is required. For example, performing the manual update of IPP for Jaba_fit.exe identifies the last update as being July 7, 2005. However, the downloaded and unzipped file has a file modification date of November 25, 2004. A comparison of the dates indicates that an incorrect or older file was somehow downloaded from the website. Thus, there is confusion as to whether the manual update worked properly. Additionally, when Jaba_fit.exe is obtained directly from the distribution CD, the date of the file is 5-May-2005. All three Jaba_fit.exe files have an associated numeric identifier of version 2.4.

3.3.4 Recommendations

R3-1: Provide IMBA Expert™ USDOE-Edition V 4.0.28 directly to each licensed DOE user. The recommended distribution method is a CD. This type of distribution will assure that all DOE users have the correct software components, since the automatic or manual updates for IMBA Expert™ USDOE-Edition have not functioned properly for all DOE users (CritRec 1).

R3-2: Create a unique identifier associated with the IPP sub-modules and implement the use of this identifier throughout development and distribution (CritRec 2).

R3-3: Provide a more obvious and consistent method to confirm that the most recent versions of all sub-modules are being used or downloaded (CritRec 3).

R3-4: Identify and place under configuration management controls all software and test files associated with IPP (e.g., runtime libraries, operational data files, automated test suite files, and test results).

R3-5: Clearly document the approach and process to control and track all future changes to the IPP software source code, compiled code, and associated files to ensure proper development, testing and operations in a manner that is easily understood by existing and future HPA staff associated with IPP development.

R3.-6: Identify and place under configuration management controls, all documents that must be retained for future reference or use by HPA staff or its user community that are associated with planning, procurements, development, implementation, testing and maintenance of the IPP software (e.g., user manual, including appendices A, B, C and D; sketches of module interfaces; configuration control processes and procedures; test approaches for major and minor releases of IPP; and summary of test results and comparison with similar applications).

R3-7: Implement a graded approach for component level and software release testing of minor releases for IPP. This approach includes an analysis to identify a subset of existing test cases and procedures and the creation of a regression test suite. This relates to the software development and implementation work activity (Section 3.6).

R3-8: Assess the capabilities of Visual SourceSafe and, where possible, replace manual procedures with Visual SourceSafe features.

Table 3.3-1 Evaluation of Software Configuration Management

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.3-1.1	Are the methods used to control, uniquely identify, describe, and document the configuration of each version or update of software and its related documentation documented?	No	No	As per personal communications, manual undocumented processes exist to control and uniquely identify the configuration of each version.
3.3-1.2	Is a configuration baseline defined and adequately controlled?	Yes	Yes	As per personal communications, a configuration baseline is defined and is manually controlled.
3.3-1.3	Does this baseline include operating system components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, the appropriate documents containing software requirements, software design, software V&V procedures, test plans and procedures, and all software development and	No	No	As per personal communications, only includes source code.

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	quality planning documents?			
3.3-1.4	Has a baseline labeling system been implemented that addresses the following: Unique identification of each configuration item? Changes to configuration items by revision?	No	No	For minor changes not expected to impact calculational values, the third set of digits is incremented. For significant changes that may affect the calulational results, the second set of digits is incremented. This applies to IMBA user interfaces (IMBA.exe) as well as all IMBA sub-modules. A major version is one in which the results of the cast-in-stone automated testing identifies differences in the calulational values. For the sub-modules both a numeric and a version-based labeling system are used. Automatic or manual updates for IMBA Expert™ USDOE-Edition have not functioned properly for all DOE users.
3.3-1.5	Is the baseline labeling system used throughout the life of the software development and operation?	No	No	A numerical labeling system exists during development whereas a date based labeling system exists for modules during user updates.
3.3-1.6	Are proposed changes to the software documented, evaluated, and approved?	Yes	Yes	Changes are informally evaluated by the HPA staff. Proposed changes related to defects are documented in a problem and reporting spreadsheet. Changes performed are documented in both the source code and in a text file sent from the HPA staff to the senior HPA staff member performing the official modifications. The impact and feasibility are informally discussed and reviewed by HPA staff.
3.3-1.7	Is software baselined prior to approval for use?	Yes	Yes	Once the software is approved for use, SourceSafe is used to archive the software.
3.3-1.8	Are only approved changes made to the baselined software?	Yes	Yes	Only approved changes are made. However, there is no formal documented change approval process. The IMBA develop team is small. Verbal and email communication is used to evaluate and approve changes.
3.3-1.9	Are software verification activities performed for the change to baselined software?	Yes	Yes	V&V activates as described in Section 3.8 are performed on the baselined software.

3.4 Procurement and Supplier Management

The procurement and supplier management activities considered here are those that were used by the IMBA developers in obtaining development tools, databases, and components. Due to the pedigree of the components and data used in the development of both IMBA products, the approach used was to

recognize that the component suppliers could be implicitly assessed due to worldwide acceptance, large user base, and industry-standard credentials. This approach is recognized in DOE G 414.1-4. Key attributes that were inferred to be assessed in this manner are as follows:

- Visual Basic® 6.0 coding
- Microsoft® features and peripheral tools (e.g., NotePad File, Calculator)
- Microsoft® development tools (e.g., Visual SourceSafe, for team-based development of software)
- SEECAL software for dose coefficients
- ICRP-based data sources

As an example of the ICRP-based data sources, the specific effective energy (SEE) data in both IMBA products were assembled directly from files of primary data calculated by HPA/NRPB using Program for LinEar Internal Age-dependent DosES (PLEIDES). PLEIDES uses a methodology similar to the one used by the ORNL program, SEECAL, and was used to prepare dose coefficients published in internationally recognized ICRP publications 67, 68, 69, 71 and 72.

3.4.1 Work Activity Evaluation and Results

Table 3.4-1 lists the criteria reviewed for this work activity and summarizes the findings. For both IMBA products, of the six criteria evaluated for this requirement, two are met, three are uncertain, and one is not applicable. Thus, the requirement is evaluated as met for both IMBA products.

3.4.2 Information Sources for Review

The user manuals for IMBA Expert™ USDOE-Edition and IPP were the primary sources of information for this work practice. These are referenced in Table 2-3 (Refs. 1 and 6).

3.4.3 Software Quality Assurance-Related Issues or Concerns

There are no SQA-related issues or concerns in this area.

3.4.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R4-1: Provide a brief written discussion on the evaluation of the major vendor(s) of components and development tools on technical and quality requirements. Of particular interest would be if QA programs were reviewed or if any of the major categories of requirements were examined, such as functionality, safety, security, and performance.

Table 3.4-1 Evaluation of Procurement and Supplier Management

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.4-1.1	Does the procurement and supplier documentation include both the technical and quality requirements including the following categories of software requirements? a. Functionality b. Safety c. Security	Yes	Yes	Because commercial off-the-shelf components were used in the development of IMBA, there is sufficient confidence in the vendors' software components and tools to infer that applicable categories of software requirements are addressed.

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	d. Performance e. Quality			
3.4-1.2	Does the procurement and supplier documentation include all documents to be provided to the customer?	Uncertain	Uncertain	Although it is suspected that Microsoft® and Visual Basic® documentation is adequate, other vendor documentation adequacy is unknown.
3.4-1.3	Do the procurement and supplier documents include requirements for or the procedures for supplier notification of defects, new releases, and other issues?	Uncertain	Uncertain	It is believed that the appropriate mechanisms were made known to notify the IMBA developers of defects, new releases, and other issues.
3.4-1.4	Do the procurement and supplier documents include requirements for or the procedures for users to report defects and requests for assistance?	Uncertain	Uncertain	The types and stature of the vendors used by the IMBA developers are such that mechanisms for reporting defects and for requesting assistance were included.
3.4-1.5	Has the delivered product been assessed or otherwise validated to ensure requirements have been met? This evidence may be included in the test results, a test summary, supplier site visit reports, or supplier QA program assessment reports.	Yes	Yes	It is likely that at least key vendor delivered products were assessed or otherwise validated to ensure that requirements were met, but there is no definitive evidence.
3.4-1.6	Has the supplier's QA program been reviewed to ensure it meets or exceeds the procurement specification requirements? This may include review the supplier's QA program through supplier assessment, supplier self-declaration, third-party certification, or other similar methods.	N/A	N/A	Considering the credentials of the key supplier vendors of IMBA software tools and components, review of QA programs was not likely performed. However, little value would have been achieved and it is judged overall not to be an appropriate use of resources and that accepting the supplier vendors' QA program based on worldwide use would be an adequate way to meet this criterion.

3.5 Software Requirements Identification and Management

3.5.1 Work Activity Evaluation and Results

Table 3.5-1 lists the criteria reviewed for this work activity and summarizes the findings for both IMBA products. Of the nine criteria evaluated for this requirement, two are met, one is not met, five are partially met, and one is not applicable. Thus, for both IMBA products the requirement is evaluated as partially met.

3.5.2 Information Sources for Review

Note that in the case of IMBA Expert™ USDOE-Edition and IPP, a formal software requirements document (SRD) was not provided. Alternative sources of information were used to evaluate this work activity.

The user manuals for IMBA Expert™ USDOE-Edition and IPP and two development contracts were the primary sources of information for this work practice. These are referenced in Table 2-3 (Refs. 1, 2, 4, and 6).

3.5.3 Software Quality Assurance-Related Issues or Concerns

At this time, the one SQA-related issue that surfaced with this area of review is regarding the lack of a software requirements document of any type to guide development of the IMBA software.

3.5.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R5-1: Develop and document software requirements for the current baseline for IPP and those pertaining to modifications and any existing requirements associated with these modifications. The level of detail should be similar to that outlined in the IMBA Expert™ USDOE-Edition contracts (Refs. 2 and 4), and include functional, performance, security (inclusive of user access control), interface and safety requirements, installation considerations, and design constraints, where appropriate.

Table 3.5-1. Evaluation of Software Requirements Identification and Management

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.5-1.1	Are the software requirements defined and documented throughout the safety software life cycle?	Partial	Partial	Software requirements are covered in part in the contract for IMBA Expert™ USDOE-Edition. While major functional requirements are covered in the user's manual and the contracts, a formal SRD was not written.
3.5-1.2	Are the software requirements uniquely identified?	No	No	Requirements for IMBA Expert™ as specified in the contractual agreement with DOE are uniquely specified by phase of development. Additional information is provided in the user's manual. Major requirements for IPP are delineated in the user's manual.
3.5-1.3	Are the requirements controlled and maintained throughout the safety software life cycle to minimize conflicting requirements and to maintain accuracy?	Partial	Partial	The requirements of IMBA Expert™ USDOE-Edition and IPP have not changed, and therefore no maintenance is required. The requirements are not controlled for either version.
3.5-1.4	Are the software requirements traceable throughout the software life cycle?	Partial	Partial	Requirements are not traceable to the design and implementation phases but to the test phase.
3.5-1.5	Are changes to the software requirements updated in any and all documents?	Yes	Yes	For the scope of this evaluation, the available documentation that reflect the requirements for both products are the user's manuals and the contract.

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.5-1.6	Are the requirements consistent with the safety system basis?	N/A	N/A	This criterion is not viewed as applicable to IMBA.
3.5-1.7	Do the software requirements address each type of the following categories? a. Functional b. Performance/timing c. Security, including user access restrictions d. Interface e. Safety	Partial	Partial	Performance, timing, safety, and security requirements have not been documented. The user's manual contains the functional and user interface requirements.
3.5-1.8	Are the software requirements complete, correct, consistent, clear, testable and feasible?	Partial	Partial	The available documents do not provide sufficient detail to develop test cases and procedures.
3.5-1.9	Can the software requirements be objectively verified and validated?	Yes	Yes	Running the software version and checking against independent analyses allow the requirements to be objectively tested.

3.6 Software Design and Implementation

IMBA Expert™ USDOE-Edition and IPP share the same mathematical sub-modules with separate user interface (aka *shell*) source modules. IMBA Expert™ USDOE-Edition source code modules are compiled with Power Basic® version 3.5, and IPP is compiled with Power Basic Console® V3.04. The IMBA Expert™ USDOE-Edition interface program, or shell, is written in Visual Basic® V6.0. The IPP interface is written in Visual Basic® 6.0, service pack 6. Updates to IMBA are always backward compatible. All updates enhance the functionality of the modules.

IMBA Expert™ USDOE-Edition source code modules are compiled for 16-bit operating systems (Win 3.1) and are compatible with 32-bit Windows® operating systems (e.g. Win98, NT, XP). IPP is complied for 32-bit operating systems and will not operate with 16-bit operating systems. Formal support for IMBA Expert™ USDOE-Edition will cease December 31, 2006.

3.6.1 Work Activity Evaluation and Results

Table 3.6-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the fifteen criteria evaluated for this requirement associated with IMBA Expert™ USDOE-Edition four are met, seven are not met, three are partially met, and one is uncertain for both IMBA products. Thus, the requirement is evaluated as not met.

3.6.2 Information Sources for Review

The primary sources of information for this work practice were the user manual for IMBA Expert™ USDOE-Edition (Phase II) version 3.2; *QA Summary*, including cast-in-stone QA, date unknown; and *Technical Annex A, Proposal to Develop Internal Dosimetry Software IMBA Expert™ USDOE-Edition for ACJ and Associates*, an attachment to a letter from Dr. A Birchall to Dr. AC James, dated March 8, 2001. Additionally, information was obtained through personal communications. The IPP update website, http://www.hpa.org.uk/radiation/publications/software/imbapro_plus/imbaupdates.htm, was referenced for information regarding manual downloads of software. These sources are referenced in Table 2-3 (Refs. 1, 5, and 7-11).

3.6.3 Software Quality Assurance-Related Issues or Concerns

IMBA was developed and is being maintained by a small development staff intimately familiar with the design. No design documentation exists or is used when modifying IMBA Expert™ USDOE-Edition or IPP. Detailed module input and output specifications were created for the original development. These are stipulated as *Commercial in Confidence* and are not available to the evaluation team.

Developer-level verification is informal. No documentation is retained. Developer testing only includes functional testing. Testing is done at the system level, and thus no code structure or logic testing is performed. Human factors' testing is not performed. Stress, load, and performance testing is not applicable.

Initial development of changes is performed by the HPA development team staff on a development version of the code. The modifications to the code are then redone by the IMBA chief architect on the master source code, which performs a review of the implementation method. An updated master version is then compiled and tested by independent HPA staff members.

3.6.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R6.-1: Document the software design of IMBA modules and IMBA user interfaces for IPP to ensure that future modifications to IMBA are implemented properly and efficiently.

R6.-2: Create, document, and maintain developer-level test cases, procedures, and results that test the code's structure and logic for all future changes to IPP. Retain test results for the appropriate time period.

Table 3.6-1 Evaluation of Software Design and Implementation

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.6-1.1	Does the safety software design describe the control flow, control logic, mathematical model?	Partial	Partial	High-level control flow provided in personal communications. No evidence of control logic or mathematical model exists.
3.6-1.2	Is the safety software design complete and sufficient to meet the safety software requirements?	Uncertain	Uncertain	Only partial documentation of the design was provided. Verification to requirements can only be indirectly evaluated through the validation process of testing to requirements.
3.6-1.3	Does the safety software design fully describe the interfaces with external components or systems?	Yes	Yes	The only external interface is the user. This interface is adequately described in the appropriate user manual.
3.6-1.4	Does the safety software design describe how the software functions internally?	No	No	No internal documentation of the software is available as per personal communications.
3.6-1.5	Does the safety software design describe the inputs	Partial	Partial	The IMBA user's manuals describe the input. No documentation was

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	and outputs including allowable or their prescribed ranges?			provided that describes the current outputs or the valid or invalid data ranges.
3.6-1.6	Does the safety software design describe the data structures and provide layouts of those structures?	No	No	No documentation exists as per personal communications.
3.6-1.7	Does the safety software (design) describe error handling strategies and the use of interrupt protocols?	Yes	Yes	The design does not describe error handling. However, as per personal communications, there is verbal confirmation that error handling has been implemented.
3.6-1.8	Has a traceability between safety software requirements and the design been performed and is documented?	No	No	As per personal communications.
3.6-1.9	Have static analyses such as code reviews been performed on safety software code modules?	No	No	As per personal communications.
3.6-1.10	Is the static analysis performed adequate coverage of critical safety software components?	No	No	As per personal communications.
3.6-1.11	Was developer unit, (integration and system) testing completed prior to system level testing?	Yes	Yes	As per personal communications, there is informal developer system level testing, including testing by an independent staff member.
3.6-1.12	Was developer testing, including unit, integration, and system level testing, planned and documented?	No	No	There is no evidence that developer testing is planned. No documentation is generated or retained related to developer testing.
3.6-1.13	Does the developer testing include tests to address functions, code structure and logic, stress and load testing, software performance, and human factors?	Partial	Partial	Developer testing only includes functional testing. Testing is performed at the system level, and thus no code structure or logic testing is performed. Human factors' testing is not performed. Stress, load, and performance testing is not applicable.
3.6-1.14	Have the results of developer testing been analyzed and documented?	No	No	As per personal communications, no documentation is retained.
3.6-1.15	Where appropriate, have reviews and testing been performed by persons independent of the activity or code module being	Yes	Yes	Chief architect reviews code modifications and then re-performs the same modifications on the master code. The master code is then rechecked by another

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	reviewed or tested?			development team member.

3.7 Software Safety

3.7.1 Work Activity Evaluation and Results

Table 3.7-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the five criteria evaluated for this requirement, associated with IMBA Expert™ USDOE-Edition four are not met, and one is partially met for both IMBA products. Of the five criteria that are partially or not met, all have little or no impact on safety decisions and can be considered of minor importance. The requirement is evaluated as not met for both IMBA Expert™ USDOE-Edition and IPP.

3.7.2 Information Sources for Review

The primary sources of information for this work practice were the review of user manual for IMBA Expert™ USDOE-Edition (Phase II) version 3.2 and personal communications. These are referenced in Table 2-3 (Refs. 1 and 7-10).

3.7.3 Software Quality Assurance-Related Issues or Concerns

Informal analysis of component failure has been performed. According to HPA staff, fault tolerant techniques were implemented in the software. IMBA software is stand-alone software. The IMBA users have a high level of knowledge of the internal dosimetry concepts and application. Failure of the software components has a negligible impact on safety decisions. Thus, this work activity has no impact on safety systems and minor at best impact on the health and safety of worker, the public, or the environment.

3.7.4 Recommendations

There is no recommendation because the failure of the software components has negligible impact on safety decisions.

Table 3.7-1 Evaluation of Software Safety

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.7-1.1	Has a hazard analysis of the software at the component level been performed and documented?	No	No	Personal communications indicate that HPA development staff is knowledgeable regarding the impact of component failure. The software design address fault tolerance methods. No formal hazard analysis has been performed. The impact of component failure is negligible to any impact on safety decisions.
3.7-1.2	Did the hazard analysis identify the potential failures, the consequences of those failures, and the probably of	No	No	No formal hazard analysis was performed.

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	occurrence associated with those failures?			
3.7-1.3	Have actions been taken to eliminate or mitigate the identified failures based upon the consequences of failure and probability of occurrence?	Partial	Partial	As per personal communications the software design and implementation includes fault tolerance methods. However, user reports have indicated that IMBA fails if two rate constants are equal and the software crashes. This failure is not trapped or resolved. This situation occurs with different input scenarios that can not be predetermined.
3.7-1.4	Was the hazard analysis periodically reviewed and reassessed for possible changes in identified hazards or the addition of new hazards?	No	No	No hazard analysis was performed.
3.7-1.5	Have changes to the hazards analysis been incorporated into the design of the safety software?	No	No	No formal hazard analysis was built into the design process and fault tolerance methods were implemented.

3.8 Verification and Validation

IMBA Expert™ USDOE-Edition software consists of a user shell that performs some calculations and prepares input files for the IMBA modules. These modules are stand-alone subroutines that perform specific functions. The completion of the IMBA modules preceded the user shell by at least five years. The IMBA modules were developed simultaneously and independently in two different languages by two different groups (Refs. 12 and 13). The outputs of the two sets of modules were compared to each other and to published values from the ICRP to ensure that identical results were obtained.

During development, IMBA Expert™ USDOE-Edition was compared to the internal dosimetry code, PLEIADES[7]. For each radionuclide, equivalent organ doses and committed effective dose resulting from acute, unit inhalation and ingestion intakes were calculated and compared with those calculated by PLEIADES. For at least one radionuclide per element, bioassay quantities resulting from acute, unit inhalation and ingestion intakes were calculated and compared with those calculated by the PLEIADES. A difference between a PLEIADES result and an IMBA result of less than 1% was considered acceptable. In some cases, differences were greater than 1% (e.g., where PLEIADES uses independent kinetics and IMBA uses shared kinetics). All differences and reasons for differences that are greater than 1% are given in appendices B and C (Refs. 8, 9, 14 and 15) of the respective IMBA user manuals.

Because of the effort involved in finding errors greater than 1% and explaining differences between IMBA and PLEIADES, it was decided not to repeat this work each time a change was made to IMBA.

[7] PLEIADES (**P**rogram for **L**in**E**ar **I**nternal **A**ge-dependent **D**os**ES**) is an NRPB in-house internal dosimetry code that has been used to calculate dose coefficients for ICRP publications. We were unable to locate any references or documentation on the code.

Instead, after each change to the IMBA interface or modules, results following the change are compared to results obtained before the change was implemented. Since the IMBA results prior to the change are compared with PLEIADES (as described above) and any differences explained, this means that IMBA results calculated following the change are indirectly compared with PLEIADES. HPA refers to this as the *cast-in-stone* method.

For most changes to the IMBA modules and the IMBA interface, no changes to bioassay or dose results are expected. All test cases that were originally compared with PLEIADES are calculated in IMBA following each change. Results from these calculations are then compared with results from IMBA prior to the change. Results that are not exactly the same following the change are highlighted. This usually indicates an unexpected effect of the change that has been made, which can be corrected until all calculated results are exactly the same as those prior to the change.

Where changes made to the IMBA modules or the IMBA interface are expected to give differences to bioassay or dose results (e.g., changes to mathematical methods), the cast-in-stone method is not valid because it compares results exactly. In these situations, results from IMBA are compared with PLEIADES directly as was done for the original V&V. Should these results pass the 1% criteria (or have valid reasons for having differences greater than 1%), these results will replace the previous IMBA baseline results and be used as the cast-in-stone baseline results for subsequent changes to the IMBA interface or IMBA modules.

3.8.1 Work Activity Evaluation and Results

Table 3.8-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the nine criteria evaluated for this requirement, two are met, one is not met, and six are partially met. Thus, for both IMBA products the requirement is evaluated as partially met.

3.8.2 Information Sources for Review

The primary sources of information used in the evaluation were the manuals that are supplied with IMBA Expert™ USDOE-Edition and IPP, personal communications with the IMBA development and support team, and a number of published papers. These are referenced in Table 2-3 (Refs. 1, 3, 6-10, and 12-18).

3.8.3 Software Quality Assurance-Related Issues or Concerns

Documentation of the parallel development and its V&V activities exist but is not available because it has been deemed to be business sensitive. A more complete document review and evaluation may have been possible if this information was accessible to the evaluation team.

3.8.4 Recommendations

There is no recommendation regarding IMBA Expert™ USDOE-Edition because of its status in the software life cycle.

R8-1: Plan, implement, and document the V&V test processes. The test processes should include both developer-level testing (component, integration, and system) as well as the acceptance testing already performed through the cast-in-stone method.

R8-2: Generate or update and review the software documents associated the SSQA activities (e.g., software requirements, SQA planning, test cases and procedures) according to the recommendations in the other work activities.

Table 3.8-1 Evaluation of Verification and Validation

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.8-1.1	Are V&V activities performed by competent staff independent of the item being verified or validated?	Yes	Yes	The entire IMBA development and support team consists of approximately fifteen individuals, with a seven member core team. The biographical sketches of key members of the team indicate that the staff is highly competent. There is no direct evidence of who performed the test procedures. However, there are individuals on the IMBA development team whose primary role is to perform V&V testing. This indicates that someone other than the primary architects tested IMBA.
3.8-1.2	Do management processes exist for performing each of the following? a. V&V activities b. Management reviews c. Independent technical reviews	Partial	Partial	There is limited documentation on the management processes. Personal communications indicate processes exist.
3.8-1.3	Do V&V activities include reviews and/or inspections of the following applicable items? (Note: These items may be combined or included with other system and software documentation.) a. Software requirements specification b. Software design c. Procurement docs d. Code modules e. Training materials f. User documentation g. Test results	Partial	Partial	The software requirements were included with the contract specification and reviewed as part of the contract process. No design document exists for review.
3.8-1.4	Do the software development and acceptance test cases and procedures include expected results?	Partial	Partial	Appendices B and C (Refs. 8, 9 14, and 15) with the minor exceptions of the Bayesian fitting and the tritium tool include expected results. There are no specific development-level test cases.
3.8-1.5	Are the software development and acceptance test cases, procedures, and test results documented?	Partial	Partial	The acceptance test cases and results are documented in appendices B and C (Refs. 8, 9, 14, and 15) of the IMBA user manual. Written test procedures are not available, but the process is described in the main section above. No test cases, procedures, or test results exist for developer testing, abnormal testing, or IMBA user interface.
3.8-1.6	Are the software development	No	No	No formal documentation is available

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	and acceptance test cases, procedures, and test results placed under configuration management?			on the configuration management of the test deliverables.
3.8-1.7	Do the software acceptance tests include the following types of tests? a. Functional b. Software performance c. Security d. Stress e. Load	Yes	Yes	The acceptance tests include functional test cases only. IMBA is a stand-alone, single-user application that has no software performance or security requirements. Stress and load testing are not applicable.
3.8-1.8	For new software versions, is regression testing performed during development and acceptance testing?	Partial	Partial	A technique referred to as cast in stone is used to compare the output of IMBA generated after a code change to the output generated before the code change. This test is used to ensure that the changes in the code did not introduce any new defects that would adversely affect the accuracy of the code. The test is run whenever a significant change in the code is made. No development-level regression testing is performed.
3.8-1.9	For new software versions, is software documentation updated and reviewed?	Partial	Partial	Code is annotated with a description of changes. The user documentation is updated when impacted by a change. There have been no changes to IMBA Expert™ USDOE-Edition V3.2 that affected the user manual. The IPP V 4.0 user manual is new and has not required any changes. No other software documentation exists.

3.9 Problem Reporting and Corrective Action

There are no formal written procedures that document or control the process of identifying and correcting defects in IMBA. However, there is a clearly delineated protocol set up among three primary IMBA team members: the IMBA North America Project Manager, the Main Contributor for IMBA Modules, and the Chief Architect. There is a feedback - bug reporting form set up on the IMBA support web page[8]. Defects can also be reported directly to the IMBA North America Project Manager or to the IMBA HPA support email address[9]. The general consensus from IMBA Expert™ USDOE-Edition users is that most issues (for IMBA Expert™ USDOE-Edition) were communicated directly with the IMBA North America Project Manager.

Once potential defects are reported, the IMBA North America Project Manager sends the feedback form to the Main Contributor. The Main Contributor reviews the information to determine if the issue is a

[8] http://www.acj-associates.com/USDOE_II_Support.htm
[9] imba@hpa-rp.org.uk

defect or user error. Once the issue is classified, the IMBA North America Project Manager is notified that the issue is under investigation or provides assistance if the issue was user related.

Problems that appear to be a defect are reviewed further, tracked in a spreadsheet, and sent to the Chief Architect. If the defect is in an IMBA sub-module, the Main Contributor for IMBA modules examines the validity. If the defect is in the user shell, the Chief Architect will investigate further. The Chief Architect controls all changes made to the IMBA software including both the IMBA sub-modules and the user shell. The appropriate member of the IMBA team then investigates the defect further and performs necessary modifications.

A description of the defect and resolution are then documented in the source code and the version number is increased. With each new release, the Main Contributor goes through the defect list to ensure that recently identified defects have been fixed. Once the defects are fixed, another member of the IMBA team independently tests the updated software. This process is discussed in V&V work activity (Section 3.8).

When the issue is resolved, the Main Contributor will email the original user requesting the issue be closed and will update the spreadsheet accordingly. The Chief Architect then uploads the new software to the appropriate IMBA website. Alternatively, IMBA can be set to automatically search for updates every time it is started.

3.9.1 Work Activity Evaluation and Results

Table 3.9-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the eight criteria evaluated for this requirement, three are met, one is not met, two are partially met, and two are uncertain. Thus, for both IMBA products the requirement is evaluated as not being met.

3.9.2 Information Sources for Review

There is no written procedure for problem reporting and corrective actions for IMBA. As a result, personal communications with the IMBA development and support team provided the information for this work activity. The IMBA support team did provide a record of problem reports and corrective actions. This is referenced in Table 2-3 (Ref. 19).

3.9.3 Software Quality Assurance-Related Issues or Concerns

No documentation for problem reports or corrective actions after 2003 was available for IMBA Expert™ USDOE-Edition. There is no documentation related to IPP problem reports or corrective actions. It is not clear whether this is the result of no reported problems or a lack of documentation.

During this evaluation process, ACJ & Associates (IMBA North America Project Manager) divested its involvement with IMBA Expert™ USDOE-Edition. The impact of this change in the business relationship on the problem reporting and corrective action work activity is unknown.

3.9.4 Recommendations

R9-1: Establish and implement an EH problem reporting and notification procedure for IMBA Expert™ USDOE-Edition. This requires implementation by DOE EH (CritRec 4).

R9-2: Implement a formal program with explicit procedures and more accessible records of corrective action activities (CritRec 5).

Table 3.9-1 Evaluation of Problem Reporting and Corrective Action

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.9-1.1	Are the practices and procedures for each of the areas below defined and documented? • Reporting problems or issues • Tracking those problems or issues • Resolving those problems or issues	Partial	Partial	There are no formal written procedures that document or control the process of identifying and correcting defects in IMBA. However, there is a clearly defined practice among three primary IMBA team members: the IMBA North America Project Manager, the Main Contributor for IMBA Modules, and the Chief Architect.
3.9-1.2	Are the above practices and procedures implemented as defined above?	Uncertain	Uncertain	There is no documentation available for IMBA Expert™ USDOE-Edition after 2003 and none for IPP.
3.9-1.3	Does a process exist for evaluating if the reported problem or issue is a software defect, error, or other source?	Yes	Yes	
3.9-1.4	Are responsibilities for the following activities identified? • Reporting issues • Approving changes • Implementing corrective actions	Yes	Yes	
3.9-1.5	Are the corrective actions implemented effective?	Uncertain	Uncertain	There is no documentation available for IMBA Expert™ USDOE-Edition after 2003 and none for IPP.
3.9-1.6	Are the defects and errors associated with the safety software defects and errors correlated with software elements?	Partial	Partial	The source code modules are updated with defect resolution information.
3.9-1.7	Has the potential impact of those defects and errors been evaluated?	Yes	Yes	
3.9-1.8	Have all users of the safety software been notified of the potential impact of the defects and errors?	No	No	The protocol has the originator of the defect notified, but there is no mechanism to notify all users.

3.10 Training Personnel in the Design, Development, Use, and Evaluation of Safety Software

The focus of this work activity is on the knowledge and skill levels of staff to perform respective duties, the activity's impact on the quality of the software products, the users' knowledge and skill level, and the activity's impact on using and interpreting the results of the software properly. This work activity contains three primary areas: 1) training of personnel in the design and development of the IMBA applications, 2) training of the operations and use, and 3) training of staff performing evaluation of the IMBA applications. The last is not applicable in this evaluation.

The HPA staff comprises a small group of specialist scientists who are recognized as experts in the internal dosimetry field. Staff members are active in ICRP and are continually sought for consulting and to perform dosimetry calculations. The staff members have authored over 30 peer reviewed articles in industry publications.

New staff members are provided on-the-job training for development practices by the experienced scientists. HPA has at least four staff members with experience in software development of scientific models for bioassay or related applications. IMBA Expert™ USDOE-Edition and IPP are developed using Visual Basic®. At least two staff members have strong skills in Visual Basic®. From resumes reviewed, HPA staff has well over 60 years of combined experience in bioassay or related applications software development. Courses in programming languages and Microsoft Windows® development have been completed by some staff members. No continuing education exists in software development or software quality engineering (including software testing).

ACJ & Associates and HPA provide training for all versions of IMBA on demand. Routine training programs are not offered because of the relatively small user base for IMBA. *IMBA Expert™ User Manual, Appendix D: Example Bioassay Cases* and online help provide an excellent basis for self study. Advanced IMBA users found the online training to be the preferred method of training.

3.10.1 Work Activity Evaluation and Results

Table 3.10-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the four criteria evaluated for this requirement, associated with IMBA Expert™ USDOE-Edition two are met, and for both IMBA products two are not met.

The two criteria not met apply to continuing education of HPA staff in software development and software quality engineering. The IMBA applications are in maintenance mode. These applications require little changes to the software design or user interface. The major enhancements focus on the mathematical algorithms and the scientific analysis behind those calculations. HPA staff continually attends discipline-specific conferences and meetings to remain abreast of any new methods and techniques in the internal dosimetry analysis community. Although these two criteria are not met, the impact on the IMBA products is minimal. Thus, the requirement is evaluated as being met.

3.10.2 Information Sources for Review

The sources used for the review include personal communications, April 2006 resumes from seven HPA staff members, the user manual for IMBA*, Appendix D: Example Bioassay Cases*, and reviews of course material. These are referenced in Table 2-3 (Refs. 10 and 20).

3.10.3 Software Quality Assurance-Related Issues or Concerns

The HPA staff knowledge and skills to implement software engineering and software quality assurance methods and practices that impact quality are obtained from job experience and personal improvement goals. Experience and education in software development or software quality assurance is viewed as secondary to expertise in computational science for internal dosimetry. The knowledge level in software testing techniques and practices, design structure, error and exception handling is unknown. No reviews were conducted of detailed test cases and procedures, detailed design, or source code to determine if best software engineering practices were being implemented.

As indicated in the work activities for V&V (Section 3.8) and model validation/performance (Section 3.11), IMBA produces the correct results.

3.10.4 Recommendations

R10-1: Monitor the quality of the IPP (e.g., number of defects released to the customer, number of user manual defects, increased development time). If a decrease in quality is observed, determine if staff training is needed. Problem reporting and corrective action processes may assist with the monitoring.

Table 3.10 Evaluation of Training Personnel in the Design, Development, Use, and Evaluation of Safety Software

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.10-1.1	Does a training or indoctrination program exist for each of the following personnel assignments? • Safety software analysis • Software development (concept to retirement) • Operations and use • Assessment or evaluation of safety software	Yes	Yes	An indoctrination program exists for training of the development staff. Formal training is available for IMBA users. Training of safety software analysis and assessment personnel is not applicable.
3.10-1.2	Does the training or indoctrination program provide for continuing education and training for each of the above personnel?	No	No	This criterion is only applicable for software development personnel. HPA does not consider software development and quality engineering continuing education high priority for the development staff.
3.10-1.3	Do continuing education and training improve the performance and proficiency for each of the above personnel?	No	No	There is no evidence of performance or proficiency improvements.
3.10-1.4	Is the training or indoctrination program designed according to the scope, complexity, and importance of the tasks, education and proficiency of the personnel?	Yes	Yes	HPA focuses on the mathematical algorithms and not on the software development practices and methods, which are viewed as having lesser importance. User training is tailored to the needs and expertise of the target audience.

3.11 Model Validation/Performance

ICRP is the primary standards organization for internal dosimetry models and methods. In particular, the ICRP specifies the structure and parameters of the biokinetic models used to calculate retention fractions and organ doses. The model specifications can at times be somewhat ambiguous. Thus, one of the more difficult tasks associated with developing an internal dosimetry code like IMBA is properly interpreting the model specifications given by the ICRP and translating these specifications into the algorithms of the code. This aspect of code development as well as the approaches to evaluating bioassay data offered to the end user can be very subjective and reflect the internal dosimetry expertise of the code developers. As indicated by the biographical sketches of the IMBA development team, they are highly qualified to interpret and implement the ICRP dosimetric models. The authors of the code have an established track record of successfully implementing ICRP dosimetric models in computer codes.

The organs and tissues of the body are modeled by ICRP as a system of compartments between which the movement of materials is governed by first-order linear differential equations. One of the most important algorithms in an internal dosimetry code is the one selected to solve the system of differential equations for the content of organs and tissues at specified times. This information is used to calculate intake retention functions, which are used to evaluate bioassay data and to calculate the number of nuclear decays that take place over specified times, which are used to calculate the dose delivered to the organ. IMBA solves this system of differential equations algebraically rather than numerically. The primary advantage of this approach is that it allows for solutions that are faster and more robust (a most likely correct IMBA-generated retention fraction). The same cannot always be said of the numerical techniques used to solve biokinetic models.

3.11.1 Work Activity Evaluation and Results

Table 3.11-1 lists the criteria reviewed for this work activity and summarizes the findings. Of the three criteria evaluated for this requirement, all three are met. Thus, for both IMBA products the requirement is evaluated as met.

3.11.2 Information Sources for Review

The sources used for the review include the user manuals for IMBA Expert™ USDOE-Edition and IPP. These are referenced in Table 2-3 (Refs. 1, 6-10, and 14-16).

3.11.3 Software Quality Assurance-Related Issues or Concerns

One important characteristic of the computational approach used in IMBA is that it will fail if the rate constants in a particular chain are not unique. This situation has been reported by users for cases where the fraction (f_1) of material absorbed by the small intestines is equal to 0.5. This is not considered a significant issue because it results in a complete failure to calculate a retention fraction (as opposed to the calculation of an incorrect retention fraction) and it has a simple workaround (increment one of the equal rate constants by a small amount).

The primary users of IMBA Expert™ USDOE-Edition are experienced internal dosimetrists. In general, the professional experience of these dosimetrists provides an expectation of results before using IMBA Expert™ USDOE-Edition. In addition, many of these users have access to other independent internal dosimetry codes. The output of these codes is compared to output from IMBA Expert™ USDOE-Edition, either as a double check of a particular result or as part of a general comparison of one code to the other. In summary, the target users of IMBA Expert™ USDOE-Edition are capable of recognizing incorrect output.

3.11.4 Recommendations

There are no recommendations to this work activity.

Table 3.11-1 Evaluation of Model Validation/Performance

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
3.11-1.1	Are the models and methods used in the safety software based upon industry/science accepted technical practices?	Yes	Yes	IMBA models and methods are based upon the recommendations of the ICRP, as interpreted by the IMBA development team. As discussed above, they are considered to be highly qualified in the interpretation and implementation of such models.
3.11-1.2	Is there evidence that output from the code was compared	Yes	Yes	The cornerstone of the IMBA Expert™ USDOE-Edition and IPP model

Criterion Number	Criterion Specification	IX	IPP	Summary Remarks
	against equivalent output from an independent code and differences resolved?			validation/performance documentation in appendices B and C (Ref 8, 9, 14, and 15) is the extensive comparison of dose and bioassay output with that generated with the computer code PLEIADES. PLEIADES is an in-house NRPB code that is used, among other things, to perform calculations for ICRP publications. PLEIADES is documented far less extensively than IMBA. There is no documentation of PLEIADES available in open literature. Nevertheless, there is considerable value in using PLEIADES for model validation/performance because it is used by the ICRP dose calculation task group. This group generates dose and bioassay quantities that are published in ICRP reports. Multiple codes like DCAL[10] and IMIE[11] are used in addition to PLEIADES for this purpose and the outputs of these codes are compared as part of the model validation/performance for the published values. The values published by the ICRP must be considered to be the "gold standard" for internal dosimetry.
3.11-1.3	Do the algorithms and numerical or analytical methods used produce valid results?	Yes	Yes	The algorithms used in IMBA to solve differential equations are analytical rather than numerical methods. This is a good approach because it tends to give the correct results in typical cases.

[10] Personal communication with Keith Eckerman, ORNL, on 3/13/06.

[11] V. Berkovski, *Application of the Internal Dosimetry Support System for Interpretation of In Vivo and Bioassay Measurements* Radiation Protection Dosimetry (89) Nos. 3–4, pp. 271–274, 2000.

4. Conclusions and Recommended Actions for Central Registry

Of the eleven work activities evaluated for IMBA products, three work activities were fully met, two partially met, and six were not met. Table 4-1 details the evaluation results for each work activity. Two work activities (problem reporting and corrective action and software configuration management) include critical recommendations that if implemented properly will increase the level of compliance for those work activities to full and partial, respectively.

Table 4-1. Work Activity Evaluation Summary

Work Activity	Evaluation
1. Software project management and quality planning	Not Met
2. Software risk management	Not Met
3. Software configuration management	Not Met
4. Procurement and supplier management	Met
5. Software requirements identification and management	Partial
6. Software design and implementation	Not Met
7. Software safety	Not Met
8. Verification and validation	Partial
9. Problem reporting and corrective action	Not Met
10. Training personnel in the design, development, use, and evaluation of safety software	Met
11. Model validation/performance	Met

This evaluation determined that IMBA fully met the criteria of model validation/performance. This criterion is one of the most important. This criterion is specific for software being considered as toolbox code in the DOE Safety Software Central Registry. The evaluation determined through these criteria that IMBA products implement industry accepted scientific methods for solving internal dosimetry scenarios properly and correctly. Although the V&V work activity was determined to be partially met, the key testing sub-activities were identified as being robust, repeatable, and consistently implemented. Results from validation activities indicate a high-quality product is delivered to the DOE users. IMBA products are in the software maintenance phase that may include significant future enhancements. The IMBA project staff is a small group of highly skilled internal dosimetry scientists that implements the work activities consistently. Although several of the work activities were only partially or not met, this has not resulted in significant defects being released to the users.

Based on the outcome of the gap analysis, IMBA Expert™ USDOE-Edition version 4.0.28, IPP version 4.0.28, and all future minor releases of IPP 4.0.x are recommended for inclusion in the DOE Safety Software Central Registry contingent upon the critical recommendations identified below being implemented by HPA and DOE EH and then reviewed by the DOE Central Registry program lead.

There are five critical recommendations that directly affect the DOE user. Three of the recommendations relate to software configuration management (work activity 3) and two are related to problem reporting and corrective action (work activity 9). Two recommendations are associated with IMBA Expert™

USDOE-Edition and the other three with IPP. Recommendation R9-1 requires implementation by DOE EH. These critical recommendations are listed below.

CritRec 1. R3-1: Provide IMBA Expert™ USDOE-Edition version 4.0.28 directly to each licensed DOE user. The recommended distribution method is a CD. This type of distribution will assure that all DOE users have the correct software components, since the automatic or manual updates for IMBA Expert™ USDOE-Edition have not functioned properly for all DOE users.

CritRec 2. R3-2: Create a unique identifier associated with the IPP sub-modules and implement the use of this identifier throughout development and distribution.

CritRec 3. R3-3: Provide a more obvious and consistent method to confirm that the most recent versions of all sub-modules are being used or downloaded.

CritRec 4. R9-1: Establish and implement a DOE EH problem reporting and notification procedure for IMBA Expert™ USDOE-Edition (Note: This is a recommendation for DOE EH).

CritRec 5. R9-2: Implement a formal program with explicit procedures and more accessible records of corrective action activities.

The gap analysis identified a total of nineteen recommendations, including the five critical recommendations, for the IMBA products based upon the criteria in DOE O 414.1C and DOE G 414.1-4. These recommendations are summarized in Table 4-2. Each recommendation has been identified uniquely using the work activity identifier and a sequence number. The recommendations have been categorized into the following areas:

- Technical Model Upgrade (TM)
- Software Quality Assurance Process/Procedure (SQAPP)
- User Interface Enhancement (UI)
- Documentation/Media (DOC)
- Training (TRAIN)
- Communications (COM)

Table 4.2 Summary of Recommendations for IMBA

	Work Activity	Category	Recommendation
1.	1. Software project management and quality planning	DOC	R1-1: Document a comprehensive and complete software project management and QA plan for the IPP, following DOE G 414.1-4, or its successor, as an acceptable method for meeting this recommendation.
2.	2. Software risk management	DOC	R2-1: Document in the software project management and quality assurance plan (see R1-1) any significant software risks and how the risks will be managed.
3.	3. Software configuration management	SQAPP	R3-1: Provide IMBA Expert™ USDOE-Edition version 4.0.28 directly to each licensed DOE user. The recommended distribution method is a CD. This type of distribution will assure that all DOE users will have the correct software components, since the automatic or manual updates for IMBA Expert™ USDOE-Edition has not functioned properly for all DOE users (CritRec 1).
4.	3. Software configuration management	SQAPP/COM	R3-2: Create a unique identifier associated with the IPP sub-modules and implement the use of this identifier throughout development and distribution (CritRec 2).

	Work Activity	Category	Recommendation
5.	3. Software configuration management	SQAPP	R3-3: Provide a more obvious and consistent method to confirm that the most recent versions of all sub-modules are being used or downloaded (CritRec 3).
6.	3. Software configuration management	SQAPP	R3-4: Identify and place under configuration management controls, all software and test files associated with IPP (e.g., runtime libraries, operational data files, automated test suite files, and test results).
7.	3. Software configuration management	DOC	R3-5: Clearly document the approach and process to control and track all future changes to the IPP software source code, compiled code, and associated files to ensure proper development, testing and operations in a manner that is easily understood by existing and future HPA staff associated with IPP development.
8.	3. Software configuration management	SQAPP	R3-6: Identify and place under configuration management controls all documents that must be retained for future reference or use by HPA staff or its user community that are associated with planning, procurements, development, implementation, testing and maintenance of the IPP software. For example user manual (including appendices A, B, C and D), sketches of module interfaces, configuration control processes and procedures, test approaches for major and minor releases of IPP, and summary of test results and comparison with similar applications.
9.	3. Software configuration management	SQAPP	R3-7: Implement a graded approach for component level and software release testing of minor releases for IPP. This approach includes an analysis to identify a subset of existing test cases and procedures and the creation of a regression test suite. This relates to the software development and implementation work activity (Section 3.6).
10.	3. Software configuration management	SQAPP	R3-8: Assess the capabilities of Visual SourceSafe and where possible, replace manual procedures with Visual SourceSafe features.
11.	4. Procurement and supplier management	DOC	R4-1: Provide a brief written discussion on the evaluation of major vendor(s) of components and development tools on technical and quality requirements. Of particular interest would be if QA programs were reviewed or if any of the major categories of requirements were examined, such as functionality, safety, security, and performance.
12.	5. Software requirements identification and management	DOC	R5-1: Develop and document software requirements for the current baseline for IPP, as well as those pertaining to modifications and any existing requirements that are associated with these modifications. The level of detail should be similar to those outlined in the IMBA Expert™ USDOE-Edition contracts (Refs. 7 and 23) and include functional, performance, security (including user access control), interface and safety requirements, installation considerations, and design constraints where appropriate.
13.	6. Software design and implementation	DOC	R6.-1: Document the software design of IMBA modules and IMBA user interfaces for IPP to ensure that future modifications to IMBA are implemented properly and efficiently.

	Work Activity	Category	Recommendation
14.	6. Software design and implementation	DOC	R6.-2: Create, document and maintain developer-level test cases, procedures and results that test the code's structure and logic for all future changes to IPP. Retain test results for the appropriate time period.
15.	8. Verification and Validation	SQAPP/DOC	R8-1: Plan, implement, and document the verification and validation test processes. The test processes should include both developer level testing (component, integration and system) as well as the acceptance testing already performed through the cast-in-stone method.
16.	8. Verification and Validation	SQAPP/DOC	R8-2: Generate or update and review the software documents associated the SSQA activities (e.g., software requirements, SQA planning, test cases and procedures) according to the recommendations in the other work activities.
17.	9. Problem reporting and corrective action	SQAPP	R9-1: Establish and implement a DOE EH problem reporting and notification procedure for IMBA Expert™ USDOE-Edition. (Note: This is a recommendation for EH) **(**CritRec 4).
18.	9. Problem reporting and corrective action	SQAPP	R9-2: Implement a formal program with explicit procedures and more accessible records of corrective action activities (CritRec 5).
19.	10. Training personnel in the design, development, use, and evaluation of safety software	TRAIN	R10-1: Monitor the quality of IPP (e.g., number of defects released to the customer, number of user manual defects, increased development time). If a decrease in quality is observed, determine if staff training is needed. Problem reporting and corrective action processes may assist with the monitoring.

A.1. DEFINITIONS

This Appendix contains some of the definitions for terms used in this report. Please refer to 10 CFR 830, DOE O 414.1C, and DOE G 414.-4 for additional definitions.

Acceptance Testing. The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment. Source: ASME NQA-1-2000.

Administrative Controls. The provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. Source: 10 CFR 830.

Cast-In-Stone. A technique used to compare the output of IMBA generated after a code change to the output generated before the code change. This test is used to ensure that the changes in the code did not introduce any new defects that would adversely affect the accuracy of the code.

Configuration Management. The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. Source: ASME NQA-1-2000.

Gap Analysis. Evaluation of the SQA attributes of specific computer software against identified criteria in DOE O 414.1C and DOE G 414.1-4.

Graded Approach. The process of ensuring that the level of analyses, documentation, and actions used to comply with requirements is commensurate with the following:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;
- the life-cycle stage of a facility or item;
- the programmatic mission of a facility;
- the particular characteristics of a facility or item;
- the relative importance to radiological and nonradiological hazards; and
- any other relevant factors.

Source: 10 CFR 830.

Hazard Analysis. The determination of material, system (including software), process, and plant characteristics that can produce undesirable consequences, followed by the assessment of hazardous situations associated with a process or activity. Source: DOE-STD-3009-94.

Hazard Controls. Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including 10 CFR 830.

(1) physical, design, structural, and engineering features;
(2) safety structures, systems and components;
(3) safety management programs;
(4) Technical Safety Requirements; and
(5) other controls necessary to provide adequate protection from hazards.

Source: 10 CFR 830.

Nuclear Facility. A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established in CFR, Part 10, Section 830. Source: 10 CFR 830.

Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. Source: 10 CFR 830.

Quality Assurance. All those actions that provide confidence that quality is achieved. Source: 10 CFR 830.

Safety. An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment. Source: DOE O 414.1C.

Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function. Source: DOE O 414.1C.

Safety-class structures, systems, and components. Structures, systems, or components, including portions of process systems, whose preventive and mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from the safety analyses. Source: 10 CFR 830.

Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or Technical Safety Requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. Source: DOE O 414.1C.

Safety Management Program. A program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment. Source: 10 CFR 830.

Safety-significant structures, systems, and components. Structures, systems, and components which are not designated as safety-class structures, systems, or components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses [10 CFR 830]. As a general rule of thumb, safety-significant SSC designations based on worker safety are limited to those systems, structures, or components whose failure is estimated to result in a prompt worker fatality or serious injuries (e.g., loss of eye, loss of limb) or significant radiological or chemical exposure to workers. Source: DOE G 420.1-1.

Safety Software. Includes safety system software, safety and hazard analysis software, design software, and safety management and administrative controls software. Source: DOE O 414.1C.

Safety Software Central Registry. A virtual repository of safety software applications, called toolbox codes, having widespread application and having a unique purpose in safety-related functions required to support DOE nuclear facilities. This term is synonymous to Central Registry. The Central Registry is managed and maintained by the DOE Office of Environment, Safety and Health.

Safety Structures, Systems, and Components. Both safety class structures, systems, and components and safety significant structures, systems, and components. Source: 10 CFR 830.

Safety System Software. Software for a nuclear facility[12] that performs a safety function as part of a structure, system or component and is cited in either DOE approved documented safety analysis or an approved hazard analysis per DOE P 450.4, *Safety Management System Policy*, dated 10-15-96, and the DEAR clause. Source: DOE O 414.1C.

Software. Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. Source: NQA-1-2000.

Software Product. The complete set of computer programs, procedures, and possibly associated documentation and data designated for delivery to a user. Source: IEEE Std-610.12-1990.

Toolbox Code. Safety software that is included in the Safety Software Central Registry.

Verification and Validation. The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements. Source: IEEE STD-610.12-1990.

[12] Per 10 CFR 830, quality assurance requirements apply to all DOE nuclear facilities including radiological facilities (see 10 CFR 830, DOE STD 1120, and the DEAR clause).

A.2. ACRONYMS

ASME	American Society of Mechanical Engineers
CANDU	CANada Deuterium Uranium
CFR	Code of Federal Regulations
COM	Communications
DEAR	Department of Energy Acquisition Regulations
DOC	Documentation
DOE	U.S. Department of Energy
EH	DOE Office of Environment, Safety and Health
HPA	United Kingdom Health Protection Agency
HRTM	Human Respiratory Tract Model
ICRP	International Commission on Radiological Protection
IEEE	Institute of Electrical and Electronics Engineers
IMBA	Integrated Modules for Bioassay Analysis
IMIE	Industrial, Manufacturing and Information Engineering
IPP	IMBA Professional Plus
ISMS	Integrated Safety Management Systems
IX	IMBA Expert™ USDOE-Edition
NQA	Nuclear Quality Assurance
NRPB	National Radiological Protection Board
OCAS	Office of Compensation Analysis and Support
ORAU	Oak Ridge Associated Universities
PLEIADES	Program for LinEar Internal Age-dependent DosES
QA	Quality assurance
RPD	Radiation Protection Division
SCM	Software configuration management
SEE	Specific effective energy
SQA	Software quality assurance
SQAP	SQA plan
SQAPP	Software quality assurance process/procedure
SPMP	Software project management plan
SRD	Software requirements document
SSC	Structure, system, or component
SSQA	Safety software quality assurance
TM	Technical model upgrade
TRAIN	Training
UI	User interface enhancement
V&V	Verification and validation

A.3. REFERENCES

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